UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

KING COUNTY, et al.,

    Plaintiffs,

    vs.

SCOTT TURNER in his official capacity as Secretary of the U.S. Department of Housing and Urban Development, et al.,

    Defendants.

Case No. 2:25-cv-00814-BJR

DECLARATION OF DR. HILLARY KUNINS

I, Dr. Hillary Kunins, declare as follows:

1.   I am a resident of the State of California. I have personal knowledge of the facts set forth in this declaration and, if called as a witness, could and would testify competently to the matters set forth below.

2.   I am the Director of Behavioral Health Services and Mental Health SF at the San Francisco Department of Public Health. In that role, I oversee the City's efforts to provide effective substance use and mental health care and promote behavioral health and wellness among all San Franciscans.

3.   DPH relies on U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) funding for several key discretionary grants, including the Building City-Wide Capacity for Community and Traditional First Responders in Overdose Response grant ("First Responders Grant").

4.   The First Responder Grant is used to train first responders to treat those experiencing an overdose, an unfortunate reality of the ongoing opioid epidemic in San Francisco. This annual grant serves a critical purpose, and SFDPH plans to apply for this grant again.

5.   I am concerned about the FY 2025 SAMHSA Notice of Funding Opportunity (NOFO) Application Guide, attached hereto as Exhibit A, which prohibits SAMHSA funds from being used to "support or provide services, either directly or indirectly, to removable or illegal aliens." SFDPH does not verify immigration status in connection with this grant, the purpose of which is to serve individuals

1   who are in immediate medical crises, and there is no reason to—and indeed, no practical ability to—

2   verify immigration status prior to providing critical emergency services.

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4   I declare under penalty of perjury that the foregoing is true and correct and that this declaration

5   was executed on July 8, 2025 at San Francisco, California.

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7   _____
    Hillary Kunins
    HILLARY KUNINS

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EXHIBIT A

FY 2025

FY 2025 Substance Abuse and Mental Health Services Administration (SAMHSA) Notice of Funding Opportunity (NOFO) Application Guide

DATE: APRIL 9, 2025

About the Application Guide

This guide will help you prepare and submit an application for a SAMHSA Notice of Funding Opportunity (NOFO).

Please review each section of this guide before you begin your application. You will find helpful guidance about key parts of the application process, including registration, required attachments, and completing the budget. The guide also provides information about federal policies and regulations you must follow if you receive federal funding.

If you have any questions about the information in this document, contact one of the SAMHSA staff members listed in Step 1 of the NOFO.

Contents

Section A: Registration and Application Submission

1. GETTING STARTED: REGISTER ON THREE REQUIRED SYSTEMS

You must be registered with these **three systems** to apply for any SAMHSA NOFO:

    1.1)   System for Award Management (SAM);

    1.2)   Grants.gov; and

    1.3)   eRA Commons.

1.1 Register Your Organization with SAM

SAM is a registry of all organizations that work with the Federal Government. When you register your organization with SAM you will receive a Unique Entity Identifier (UEI). You cannot apply for an award without a UEI.
If you are new to SAM:

- Go to https://www.sam.gov. Create a user account.

- Follow the instructions to register your organization and obtain a UEI.

  - *A UEI is required for both grant recipients and all sub-recipients.*

- SAM.gov will send you an email when your registration is active.

- **Start the SAM registration process at least 6 weeks before the NOFO application is due**. It can take up to 10 business days for your registration to activate and to receive your UEI.

- After you receive your UEI, you must keep your account active by updating your information every 12 months.

If you already have a SAM account:

- Log in and confirm that your organization's registration is active. The expiration date appears on the registration page.

- If your organization's registration has expired, it will take 48 to 72 hours to renew. **Note that Grants.gov (see 1.2 in this Section) rejects applicants with an expired registration.**

- If you can't log in because your account is inactive, please allow up to 14 days for SAM.gov to renew your account.

You must keep your SAM registration active (both recipients and sub-recipients) with up-to-date information while your organization has an active federal award or an application under consideration by an agency. **This does not apply if you are an individual or federal agency that is exempted from those requirements under** 2 CFR § 25.110.

1.2   Register on Grants.gov

Grants.gov is an online portal for submitting federal award applications. It requires a one-time registration. eRA Commons registration (see 1.3 in this Section) is separate, but you can register for both at the same time.

- Go to https://grants.gov/register to register.

- *The person who submits your application must be registered with Grants.gov as the Authorized Organization Representative (AOR) for the UEI number entered in box 8c on the first page of the SF-424.* See the Grants.gov Online User Guide.

1.3   Register on eRA Commons

eRA Commons allows applicants, award recipients, and federal staff to securely share, manage, and process award-related information. Your organization needs a valid and active UEI from SAM.gov to complete the eRA Commons registration.

Your application will not be accepted if your organization does not register or have an active and valid eRA Commons Principal Investigator/Project Director (PI/PD) account by the NOFO deadline. **No exceptions will be made.**

If you are new to eRA Commons:

- Register to receive your organization's eRA Commons Username. With this username, you can access your electronic submission, receive notifications on your application status, and get award information.

- Identify your Signing Official (SO) who will complete the Register Institution Form. This person must be registered as the AOR role in Grants.gov and be listed in the Authorized Representative section (#21) on page 3 of the SF-424.

- The SO must complete and submit the online Register Institution form. This is a one-time registration. For instruction on how to register, go to Register in eRA Commons.

- After completing the Register Institution form, the SO will receive an email with registration approval and an eRA Commons User ID for the SO account role.

- Once the account is active, the SO can create additional user accounts for the organization, including the required account for the PI/PD.

- If the person in the SO role for your organization needs to be changed, contact the eRA Service Desk for guidance on how to make this change.

1. The SO **must** create a Commons user account with the PI/PD role. The PD must complete setting up their user account.

2. The person assigned the PI/PD role in eRA will be designated by SAMHSA as the Project Director (PD).

3. The PD's eRA Commons username **must** be entered in Line 4 (Applicant Identifier) of the SF-424

4. The PD's information **must** be entered in **Section 8f** (name and contact information of the person to be contacted on matters involving this application) on page 1 of the SF-424.

5. The same person cannot be entered on the form as the SO and the PD.

6. More than one person can hold each role, but only the eRA Commons account holders named on the SF-424 are designated as the contact persons for the application.

2. COMPLETE YOUR APPLICATION

After successfully registering with SAM, Grants.gov, and eRA Commons, download all required application components.

2.1   Paper Copies of Application Materials

You may request paper copies if your organization cannot access high-speed internet or download the required documents.

Email the Division of Grant Review at dgr.applications@samhsa.hhs.gov to receive paper copies.

Tip: Sign up for Grants.gov updates to receive SAMHSA NOFO notifications.

2.2   Standard Application Components

The following table includes a description of each required document and where it can be found.

IMPORTANT: All files uploaded with the Grants.gov application **MUST** be in **Adobe PDF.** See Formatting Requirements and System Validation for SAMHSA Grant Applications.

#	Standard Application Components	Instructions	Where to Find Document
1	SF-424 Application for Federal Assistance Form	**Complete all sections of this form.** ✓ *Line 4 – Applicant Identifier.* Enter the PD's eRA Commons username. ✓ *Section 8b. Employer/Taxpayer Identification Number (EIN/TIN).* If your organization is already registered with the Payment Management System (PMS), enter the 12-character EIN. ✓ *Section 8d: Address.* Use your organization's legal mailing address. The address cannot be a P.O. Box. ✓ *Section 8f: Name and contact information of person to be contacted on matters involving this application.* Enter the PD's name, title, organization, phone, and email. ✓ *Page 3 – Authorized Representative.* Enter the SO's name, title, phone, and email. **IMPORTANT:** • All Notices of Award (NoAs) will be emailed via eRA Commons to the PD and the SO identified on the SF-424. • The PD listed on the SF-424 must match the PD in the Personnel Costs Section in the budget.	Grants.gov/forms or sample-sf-424-new-awards.pdf (samhsa.gov)
2	SF-424A Budget Information – Non-Construction Programs Form	Fill out Sections A, B, D, and E. Only complete Section C if there is a match requirement.	Grants.gov/forms
3	Project/Performance Site Location(s) Form	Provide complete information on the physical location of the site or sites where you will implement the project. You may not use a P.O. Box.	Grants.gov/forms
4	Project Abstract Summary	**Write a one-page project abstract.** Your abstract should include: ✓ A project summary within the first five lines. SAMHSA will use this summary in publications, reports to Congress, or press releases if your project is funded. ✓ Project name ✓ Service population, including demographics and clinical characteristics ✓ Strategies or interventions you plan to implement ✓ Project goals and measurable objectives, including the number of people your project will serve annually and throughout the entire project	Not Applicable

#	Standard Application Components	Instructions	Where to Find Document
5	Project Narrative Attachment	**The Project Narrative is your response to the Evaluation Criteria (Part 4 of the NOFO).** ✓ Provide a detailed response to each of the evaluation criteria. ✓ Do not exceed the number of allowable pages as described in the NOFO. ✓ Attach the Project Narrative file as an Adobe PDF inside the Project Narrative Attachment Form.	Not Applicable
6	Budget Justification and Narrative Attachment	**Submit a detailed Budget Narrative with Budget Form SF-424A.** ✓ It is highly recommended that you use the Budget Template. ✓ Follow the guidelines in the Budget and Justification section. This section details what budget categories to include and how to separate amounts for different program functions or activities. ✓ Follow any existing federal award or SAMHSA guidelines that describe how budgeted amounts should be separated for different program functions or activities. ✓ **Submit the budget narrative and justification with the file name "BNF."**	SAMHSA Website
7	SF-424B Assurances for Non-Construction Form	You must acknowledge that you have read and understand the list of assurances provided on the SAMHSA website. By checking the box marked "I Agree" and signing the SF-424 you agree to the assurances listed on the SF-424B.	SAMHSA Website
8	Grants.gov Lobbying Form SF-LLL Disclosure of Lobbying Activities Form	Federal law prohibits the use of appropriated funds for publicity or propaganda purposes or for the preparation, distribution, or use of the information designed to support or defeat legislation pending before Congress or state legislatures. All applicants must submit the Grants.gov Lobbying Form. If your organization participates in lobbying activities, you must also submit a signed copy of the Disclosure of Lobbying Activities Form (SF-LLL).	Grants.gov/forms
9	Other Attachments Form	Refer to *Other Supporting Documents*.	

Other Supporting Documents

You must submit the supporting documents listed in the following table with your application, along with the Standard Application Components. **Attach each document (Adobe PDF format only) using the Other Attachments Form in eRA ASSIST or Grants.gov**.

#	Supporting Documents	Instructions	Where to Find the Document
1	Charitable Choice Form SMA 170 (Attachment 10 or 11)	*Required only for awards that fund substance misuse treatment or prevention services** Review Part 3 of the NOFO to see if you must submit a Charitable Choice Form (SMA 170).	SAMHSA Website
2	Biographical Sketches and Position Descriptions (Attachment 5)	See **Biographical Sketches and Position Descriptions for instructions**. ✓ These documents allow SAMHSA to evaluate the qualifications of program staff and to understand the duties they will perform. ✓ Formatting requirements do not apply to these documents.	Biographical Sketches and Position Descriptions
3	Confidentiality and SAMHSA Participant Protection/Human Subjects (Attachment 6)	**Describe the safeguards your organization has in place to protect individuals from risks associated with their participation in the program.** The Confidentiality and SAMHSA Participant Protection/Human Subject Guidelines section of this document covers requirements related to confidentiality, participant protection, and the protection of human subjects regulations. Note that there are different requirements based on the type of grant program.	Services grants Section B Training grants (Section C) Capacity building grants (Section D)
4	Additional Documents in the NOFO	**Review Part 3 of the NOFO to find out if there are additional attachments that you must include in your application.**	Part 3 of the NOFO
5	Current Negotiated Indirect Cost Rate Agreement (NICRA) or Cost Allocation Plan (Attachment 9)	**If your organization has a negotiated cost rate agreement or cost allocation plan, submit it with your application. If your rate agreement is currently being negotiated, submit proof of proposal submission.** SAMHSA will review your organization's NICRA to ensure that your budget reflects the negotiated rate.	Not applicable

#	Supporting Documents	Instructions	Where to Find the Document
6	Other Active Federal Awards	**Provide a list of your organization's active federal awards with the grant number, designated key personnel, and their individual levels of effort for each award.** Key personnel or other grant-supported staff must not exceed 100% level of effort across all current federal and non-federal funding sources.	Not Applicable

2.3   Additional Documents for Submission

The SAMHSA website has additional materials you may need to complete your application.

3. SUBMIT YOUR APPLICATION

3.1   How to Submit Electronically (eRA ASSIST or Grants.gov Workspace)

After you complete all registration and application requirements, **you must electronically submit your application to Grants.gov.** You may do this using one of two methods:

1. eRA Common's ASSIST, which will automatically route your application to Grants.gov; or

2. Grants.gov Workspace.

Regardless of how you submit, your application will be subject to the same registration requirements, completed with the same data items, routed through Grants.gov, validated against the same agency business rules, assembled in a consistent format for review consideration, and tracked in eRA Commons.

> **Tip:** Submit your application 24–72 hours before the deadline. This allows time to fix submission errors or issues and to resubmit your application if needed.

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How to Submit with eRA ASSIST

SAMHSA strongly recommends that you use eRA ASSIST to prepare your application using the SF-424 forms, to submit through Grants.gov to SAMHSA and other participating agencies, and to track your application. eRA ASSIST will allow you to ensure your application is submitted error-free in Grants.gov. NOTE: ASSIST requires the ID you received when you registered in eRA Commons.

To submit your application using eRA ASSIST:

1. Visit eRA Modules, User Guides, and Documentation | Electronic Research Administration for instructions.

2. Use the "ASSIST Validate Application" function to check your draft application for any errors or warnings. You must correct errors before your application can be successfully submitted.

3. Once no errors or warnings are found, you can submit your application.

How to Submit with Grants.gov Workspace

Grants.gov Workspace allows you to collaborate with others on the various forms within the application.

To submit your application using the Grants.gov Workspace, see Grants.gov Workspace Overview.

3.2   How to Request a Waiver to Submit a Paper Application

SAMHSA does not accept paper applications except in rare circumstances.

You may request a *waiver of electronic submission* if you do not have the technology to apply online or your location has no internet connection.

SAMHSA must approve a waiver of this requirement in advance. **You must send a written request to the Division of Grant Review at least 15 days before the application due date.**

Contact SAMHSA's Division of Grant Review at dgr.applications@samhsa.hhs.gov with your request or questions about the process.

3.3   Deadline

Your electronic application must be error-free, **submitted,** *and* **validated** by Grants.gov and eRA Commons no later than 11:59 p.m. Eastern Time on the application due date. Applications submitted after the due date will not be considered.

See Section 4.1 for more information about validation.

3.4   How to Get Assistance If You Have Trouble Submitting

If you have problems in Grants.gov, contact the Grants.gov Service Desk:

- Email: support@grants.gov.

- Phone: 1-800-518-GRANTS. The Grants.gov Service Desk is available 24 hours a day, 7 days a week, except on federal holidays.

Make sure you receive a case, ticket, or reference number that documents the issues with Grants.gov.

Additional support is also available from the eRA Commons Service Desk:

- Submit a service request ticket: http://grants.nih.gov/support/index.html

- By phone: 301-402-7469 or (toll-free) 1-866-504-9552. The eRA Commons Service desk is available Monday through Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

4. AFTER SUBMITTING YOUR APPLICATION

After you submit your application, it will go through two validation processes with both Grants.gov and eRA Commons. Your application must pass both validations successfully before SAMHSA receives it.

4.1   System Validation and Tracking

First: Grants.gov Validation

After you successfully submit your application, Grants.gov will:

1. Email you to confirm receipt of your application and provide a tracking number.

2. Email you again to validate your application or reject it due to errors. If Grants.gov says your application was "Rejected with Errors," you must address all errors and resubmit.

> **Tip:** Your Grants.gov tracking number is the only indication that Grants.gov received and validated your application.
>
> If you do not receive a Grants.gov tracking number, contact the Grants.gov support center for assistance.

Once Grants.gov validates your application, it will go through the eRA Commons validation process.

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You can check your application status at any time by logging into your Grants.gov Workspace account. Note: this only confirms that an application was successfully retrieved by eRA Commons. Thereafter in the process, eRA Commons reviews and processes the applications independent of Grants.gov and does not report the status to Grants.gov.

Second: eRA Commons Validation

eRA Commons will email you if it finds errors during the validation process. There is a difference between warnings and system errors**.**

- *If you receive a "Warning" notification:*

  - ✓ ***You are not required to resubmit the application****.*

  - ✓ The email notification will describe the reason for the warning.

  - ✓ You can then decide whether to correct and resubmit the application.

- *If you receive a "Systems Error" notification:*

  - ✓ ***You must correct the error and resubmit your application.***

  - ✓ You must resubmit the application through Grants.gov before the due date and time.

  - ✓ When resubmitting an application after making revisions, ensure the **Project Title is identical to the Project Title in the originally submitted application**. In addition, check the Changed/Corrected Application box in #1.

  - ✓ Once you correct and resubmit your application, check your application status in eRA Commons to ensure it was successfully submitted.

You can track your application's progress in eRA ASSIST at any time.

1. Look for a link in ASSIST called "View Submission Status Details."

2. The link will show a 7-digit agency tracking number.

3. Click on the link to verify that your application successfully processed and was submitted to SAMHSA.

4.2   System or Technical Issues

System problems are rare. However, if a system failure in SAM, Grants.gov, or eRA Commons prevents you from successfully submitting your application on time, take these steps right away:

- If the issue occurred in eRA Commons, contact the eRA Service Desk and submit a web ticket.

- Email SAMHSA's Division of Grant Review at dgr.applications@samhsa.hhs.gov within **1 business day after the due date**.

- Provide your case number and any email from SAM, Grants.gov, or eRA Commons that allows SAMHSA to obtain documentation about what caused the error.

- SAMHSA will determine if you met the requirements and deadlines and made no errors that caused your submission to fail. No exceptions for submission are allowed when user error is involved.

Section B: Confidentiality, Participant Safety, and Protection of Human Subjects/Services Grants (Attachment 6)

This section tells you what to address in Attachment 6 of your application. In Attachment 6, you need to show how you will protect individuals from risks associated with their participation in SAMHSA-funded projects.

All applicants for grants providing services (including those who plan to obtain **Institutional Review Board [IRB] approval**) **must** address all the following elements.

There is no page limit for your response to this section.

Required Elements for All Applicants

1. **Protect Participants and Staff from Potential Risks**

   - Identify and describe possible physical, medical, psychological, social, and legal risks or potential adverse effects your project **participants** may be exposed to.

   - Identify and describe possible physical, medical, psychological, social, and legal risks, or potential adverse effects, your project **staff** may be exposed to.

   - Describe how you will minimize or protect participants and staff against potential risks, including risks to confidentiality.

   - Outline your plan to provide assistance if participants or project staff experience adverse effects. Include, if any, alternative treatments that will be available to participants.

   SAMHSA considers the following responses unacceptable or incomplete:

   - Stating that your program poses **no risks** to participants. If your program involves providing services and/or involving individuals, potential risks or adverse events are likely to exist.

   - Addressing potential risks to participants but not addressing risks to staff.

   - Failing to describe how your organization will provide assistance to participants who may experience adverse effects.

   - Failing to describe whether alternative treatments will be available to those participants.

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2. Fair Selection of Participants

- Explain how you will recruit and select participants and ensure all populations have equal opportunity to take part in the program.

- If you have identified individuals in your service area who you believe should be excluded from the program, explain the reason(s) for this exclusion.

> SAMHSA considers the following responses unacceptable or incomplete:
>
> - Not explaining reasons for including or excluding participants.
>
> - Not explaining how your program will select participants.

3. Absence of Coercion

- *You must address this item if your budget includes funding for incentives. If you are using incentives for this program, but they are not paid for by this grant, provide this information and identify the funder.*

- Describe how you will use grant-funded incentives (e.g., gift cards, bus passes, or gifts). If you plan to implement a contingency management program[1], specify the evidence-based model your program will use and briefly justify its use with your service population(s).

- Provide a justification that the use of grant-funded incentives is appropriate, judicious, and conservative. Also explain how you ensure the incentives do not provide an "undue inducement" that removes the voluntary nature of participation.

- Describe the process you use to inform participants that they may still receive services even if they choose not to participate in or complete the data collection component of the program.

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[1] Contingency management is an evidence-based therapeutic intervention that involves providing incentives to individuals to reinforce desired behaviors.

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SAMHSA considers the following responses unacceptable or incomplete:

- Stating that you do not plan to use incentives but including funding for incentives in your budget or describing the use of grant-funded incentives in your Project Narrative.

- Not providing a plan of how you will tell potential participants that they may receive services even if they choose not to participate in or complete the data collection component of the project. Stating you will tell participants this information or saying you will ensure they know their rights is not sufficient.

4. Data Collection

- Identify who you will collect data from. This may include participants, clients, family members, teachers, staff, or others.

- Describe the data collection procedures you will use and specify the sources for obtaining data. These sources may include school records, interviews, psychological assessments, questionnaires, observation, or other sources.

- State if you will be collecting specimens and provide the type(s) (e.g., urine or blood) your program may collect. Indicate if the specimens will be used for purposes other than evaluation.

- Provide copies of all available data collection instruments and interview protocols that you plan to use in *Attachment 2, "Data Collection Instruments/Interview Protocols,"* of your application. You may also provide a web link to standardized instruments or protocols you plan to use.

SAMHSA considers the following responses unacceptable or incomplete:

- Not clearly identifying the individuals who you will collect data from.

- Describing the use of drug testing in the Project Narrative but not providing information about specimen collection.

- Not including data collection instruments or interview protocols (or links to online instruments) in Attachment 2.

- Not including how or where you will collect data, such as with paper surveys or electronic surveys and in a school or clinic setting.

5. **Privacy and Confidentiality**

- Explain how you will ensure privacy and confidentiality, including:

  ✓ Where you will store collected data.

  ✓ Who will have access to collected data.

  ✓ How you will keep the identity of participants private. For example, your program may use a coding system on data records, limit access to records, or store participant identifiers separately from data.

- **NOTE:** Recipients that are providing substance misuse services in their program must specify that they will maintain records according to the provisions of Title 42 of the Code of Federal Regulations (CFR), Part II, Subpart B.

SAMHSA considers the following responses unacceptable or incomplete:

- Not explaining where you will store data and how you will keep participants' identities confidential.

- Not clearly specifying who will have access to the data.

- If providing substance misuse services, not specifying that you agree to maintain the confidentiality of substance use disorder client records according to the provisions of 42 CFR, Part II, Subpart B.

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6. **Adequate Consent Procedures**

- Include the sample consent forms listed below in *Attachment 3 "Sample Consent Forms"* of your application. If needed, provide forms in languages that are used by your program participants.

  ✓ Informed consent for program participation.

  ✓ Informed consent for participation in data collection, which also notifies participants that they may still receive services if they choose not to participate in or complete the data collection component of the project.

  ✓ Informed consent for the exchange (either releasing or requesting) of confidential information.

  ✓ Informed consent for youth participants (individuals 18 and under).

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- Explain how you will obtain and document consent for each of the following groups. (For example. you may read the consent forms to potential participants, ask them questions to ensure they understand the forms, or give them copies of what they sign.)

  ✓ youth,

  ✓ older adults,

  ✓ people with limited reading skills, and

  ✓ people who do not use English as their first language.

Additional Instructions for Consent Forms:

1. Forms should be easy to understand.

2. The consent forms should never do the following:

   a. Imply that a participant waives or appears to waive any legal rights.

   b. Imply that a participant cannot end involvement with the program.

   c. Imply that your program or its agents will be released from liability for negligence.

SAMHSA considers the following responses unacceptable or incomplete:

- Not providing copies of all sample consent forms in Attachment 3. Providing a combined program participation and data collection consent form is unacceptable if the participant cannot consent to each item separately.

- Providing consent forms that use passive consent instead of informed consent.

- Not providing details on how you will obtain consent for youth.

- Not providing details on how you will obtain consent for non-English-speaking populations who will receive services or training.

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7. **Risk/Benefit Discussion**

- Discuss why the risks you identified in #1 *(Protect Participants and Staff from Potential Risks)* are reasonable compared to the expected benefits for program participants. Discuss the expected benefits for program participants.

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> SAMHSA considers the following responses unacceptable or incomplete:
>
> - Stating there are **no risks** to participants in the first element and noting that this element is therefore not applicable.
>
> - Not mentioning any expected benefits to program participants.

PROTECTION OF HUMAN SUBJECTS REGULATIONS

You will need to determine if Protection of Human Subjects Regulations applies to your project. If it does, you must submit the following required documentation.

SAMHSA expects that most grant recipients will not have to comply with the Protection of Human Subjects Regulations (45 CFR 46), which require IRB approval. However, your program could meet the regulation's criteria for research involving human subjects.

You do not need IRB approval at the time of award, but you must provide the appropriate documentation before you enroll participants.

If your program must comply with Human Subjects Regulations, you must do the following:

- Explain how your organization will obtain IRB approval.

- Provide documentation that your organization has an "Assurance of Compliance" on file with the Office for Human Research Protections (OHRP).

- Provide documentation that your organization obtained IRB approval before enrolling participants.

Information about Human Subjects Regulations is available from OHRP at www.hhs.gov/ohrp or (240) 453-6900. For SAMHSA-specific questions, contact the Government Project Officer listed in Agency Contacts in the NOFO.

Section C: Confidentiality and Participant Protection/Training Grants (Attachment 6)

This section should <u>only</u> be completed by applicants for training/technical assistance grants. Applicants for grants providing services must respond to Section B.

This section tells you what to address in Attachment 6 of your application. In Attachment 6, you need to show how you will protect individuals from risks associated with their participation in SAMHSA-funded training/technical assistance projects.

<u>All applicants must </u>address all the following elements.

There is no page limit for your response to this section.

<u>Required Elements for All Applicants</u>

1. **Protect Participants and Staff from Potential Risks**

   - Identify and describe possible physical, medical, psychological, social, and legal risks or potential adverse effects your project **participants** may be exposed to.

   - Identify and describe possible physical, medical, psychological, social, and legal risks or potential adverse effects your project **staff** may be exposed to.

   - Describe how you will minimize or protect participants and staff against potential risks.

   - Outline your plan to provide assistance if participants or staff experience adverse effects.

   > SAMHSA considers the following responses unacceptable or incomplete:
   >
   > - Stating that your program poses **no risks** to participants.
   >
   > - Addressing potential risks to participants but not addressing risks to staff.
   >
   > - Failing to describe how your organization will provide assistance to participants who experience adverse effects.

2. **Data Collection**

   - Describe the data collection procedures you will use and specify the sources for obtaining data.

- Provide copies of all data collection instruments you plan to use in *Attachment 2, "Data Collection Instruments."* You may also provide a web link to standardized instruments or protocols you plan to use.

> SAMHSA considers the following responses unacceptable or incomplete:
>
> - Not including data collection instruments (or links to online instruments) in Attachment 2.

3. Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality, including:

  - ✓ Where you will store collected data.

  - ✓ Who will have access to collected data.

- How you will keep the identity of participants private.

> SAMHSA considers the following responses unacceptable or incomplete:
>
> - Not explaining where you will store data and how you will keep participants' identities confidential.
> - Not clearly specifying the individuals who will have access to the data.

4. Adequate Consent Procedures

- In *Attachment 3, "Sample Consent Forms,"* provide the sample consent form for participation in your training project which includes a separate consent line for participation in data collection.

- Explain how you will obtain and document consent for each of the following groups. For example, you may read the consent forms to potential participants, ask them questions to ensure they understand the forms, or give them copies of what they sign.

  - ✓ youth,

  - ✓ older adults,

  - ✓ people with limited reading skills, and

  - ✓ people who do not use English as their first language.

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Additional Instructions for Consent Forms:

1. Forms should be easy to understand.

2. The consent forms should never do the following:

    a. Imply that a participant waives or appears to waive any legal rights.

    b. Imply that a participant cannot end involvement with the program.

    c. Imply that your program or its agents will be released from liability for negligence.

SAMHSA considers the following responses unacceptable or incomplete:

- Not providing copies of sample consent forms in Attachment 3.
- Not providing details on how you will obtain consent for youth unless your program doesn't work with this population.
- Not providing details on how you will obtain consent for non-English-speaking populations who will receive training.

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5. **Risk/Benefit Discussion**

- Discuss why the risks you identified in #1 *(Protect Participants and Staff from Potential Risks)* are reasonable compared to the expected benefits for program participants. Discuss the expected benefits to program participants.

SAMHSA considers the following responses unacceptable or incomplete:

- Stating there are **no risks** to participants in the first element and noting that this element is therefore not applicable.
- Not mentioning any expected benefits to program participants.

Section D: Confidentiality and Participant Protection/Capacity Building Grants (Attachment 6)

This section should <u>only</u> be completed by applicants for capacity building grants. Applicants for grants providing services must respond to Section B.

This section details what to address in Attachment 6 of your application to show how you will protect individuals from risks associated with their participation in SAMHSA-funded projects.

<u>All applicants must </u>address all the following elements.

There is no page limit for your response to this section.

<u>Required Elements for All Applicants</u>

1. **Fair Selection of Participants**

   - Explain how you will recruit and select individuals to be involved in capacity building activities, such as work group members, individuals with lived experience, or consumers.

   - If you are providing external trainings, explain what criteria you will use to determine who is eligible to take your trainings. Explain why your inclusion/exclusion criteria are appropriate for this grant.

   > SAMHSA considers the following response unacceptable or incomplete:
   >
   > - Not explaining how your program will recruit and select participants for capacity building activities.
   > - Your application indicates you're providing external trainings, but you do not explain what criteria people must meet to participate.

2. **Data Collection**

   - Describe the data collection procedures you will use and specify the sources for obtaining data.

   - Provide copies of all available data collection instruments and interview protocols that you plan to use in *Attachment 2, "Data Collection Instruments/Interview Protocols,"* of your application.

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> SAMHSA considers the following responses unacceptable or incomplete:
>
> - Not including data collection instruments (or links to online instruments) in Attachment 2.

3. Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality, including:

  - ✓ Where you will store collected data.

  - ✓ Who will have access to collected data.

  - ✓ How you will keep the identity of individuals private, particularly consumers and those with lived experience. For example, your program may use a coding system on data records, limit access to records, or store participant identifiers separately from data.

Section E: Budget and Justification Narrative

Your application must include a detailed budget and narrative justification. In the budget, include federal and non-federal expenditures broken out by the object class cost categories listed on SF-424A − Section B (Budget Category) for non-construction awards.

- Your budget must match the costs identified on the SF-424A and the total costs on the SF-424.

- The budget and justification must be consistent with the Project Narrative.

- Your justification must be concrete and specific. It should explain the basis of each proposed cost in your budget and how it was calculated.

  - Examples to consider when justifying the basis of the estimates can be ongoing activities, market rates, quotes received from vendors, or historical records. Your proposed costs must be reasonable, allowable, allocable, and necessary for the supported activity.

- Refer to the program specific Funding Restrictions/Limitations in the NOFO (Step 1), Standards for Financial Management and Standard Funding Restrictions, and 2 CFR 200 for applicable administrative requirements and cost principles.

Awards are generally for periods of performance (budget periods) of 1–5 years. SAMHSA bases the release of subsequent year funds on the submission and approval of your progress report(s) and any other required reports. Funding beyond the first-year budget period is subject to availability of funds and satisfactory progress of your program. SAMHSA evaluates progress based on required performance measures, satisfactory achievement of goals and objectives, providing services to the projected number of people specified in the application, and satisfactory resolution of barriers and challenges.

SAMHSA Budget Template

SAMHSA strongly recommends using the budget template to complete the Detailed Budget and Narrative Justification. See SAMHSA Application Forms and Resources for instructions and to download the template and other guidance documents.

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Completing the SF-424A: Budget Cost Categories

Direct Costs: Costs charged directly to a federal award are typically incurred specifically for that federal award. Costs that otherwise would be treated as indirect costs may also be considered direct costs if they are directly related to a specific award (2 CFR 200.413).

Personnel Costs: Explain personnel costs by providing the names and titles of each staff member involved in the project, along with their percentage level of effort, proposed hours, and annual salary. If a staff member has not been identified, you may write "To Be Hired" as the Name. You may not use award funds to pay an individual's salary exceeding Executive Level II. The current salary limitation can be found in the most recent SAMHSA Standard Terms and Conditions. An individual's base salary, per se, is NOT constrained by the statutory provision for a limitation of salary. This limitation applies to SAMHSA awards, subawards, subcontracts, and cooperative agreements. However, it does not apply to consultants.

The Project Director name, base salary, and percentage level of effort must be listed in the budget narrative justification, including in-kind, and must match the name listed on the SF-424, section 8f.

NOTE: If your organization receives an award and chooses to move forward with filling a Key Personnel position before receiving formal SAMHSA approval, this will be done at your organization's own risk. If SAMHSA's review of the Key Personnel request results in the proposed individual not being approved for the position, you must submit a qualified candidate for the Key Personnel position. SAMHSA will not be liable for any costs incurred or pay for the salary of a Key Personnel position that it has not approved.

Fringe Benefits: Fringe benefits typically include such items as health insurance, taxes, unemployment insurance, life insurance, retirement plans, tuition reimbursement, and paid absences. Fringe benefits are recoverable in accordance with your organization's federally approved indirect cost rate agreement, if applicable, or the organization's accounting practices, provided those practices are consistent with federal cost principles and result in a fair and equitable allocation of fringe benefits.

Travel: List travel costs for local and/or long-distance travel. For local travel, enter the mileage rate, number of miles, reason for travel, and staff member/consumer completing the travel. The budget should also reflect the travel expenses like airfare, lodging, parking, and any per diem for each person and trip associated with participating in meetings and other proposed trainings or workshops. Name the traveler(s), if possible, describe the purpose of the travel, provide number of trips involved, the destinations, and the number of individuals you seek funds for. Ensure that the travel rates used comply with the allowable reimbursable U.S. General Services Administration's (GSA) rates.

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Equipment: List equipment costs (such as large items of medical equipment) and justify the need for the equipment. You must also provide the status of current equipment when requesting funds for the purchase of items that meet the definition of equipment (a unit cost of $10,000 or more and a useful life of 1 or more years).

Supplies: Include the programmatic items (such as examination gloves) necessary for program implementation. In contrast, note that general office supplies (such as paper and pencils) are typically considered as part of indirect costs and can be recovered through a federally approved indirect cost rate or the de minimis indirect cost rate.

Per 2 CFR 200.314, property will be classified as supplies if the acquisition cost is less than $10,000. Items such as laptops, tablets, and desktop computers are classified as a supply if the value is less than the $10,000 equipment threshold.

Vendor Contracts/Subawards & Subcontracts/Consortiums/Consultants: Provide an explanation about the purpose, basis for how you estimated costs, and specific deliverables. You must ensure that your organization has adequate procurement and merit review systems with fully developed written procedures for awarding and monitoring vendor contracts and subawards/subcontracts, respectively. You must notify potential subrecipients that they must provide you with their UEI number (see 2 CFR Part 25). For consultant services, list the total costs for all consultant services. In the narrative justification, identify each consultant, the services they will perform, total number of days, travel costs, and total estimated costs.

NOTE: To help you classify costs and relationships, note that vendor contracts are for obtaining goods and services (e.g., examination gloves provided by a medical supply company). In contrast, subawards/subcontracts are for carrying out a portion of a federal award (e.g., a health care clinic providing substance misuse treatment services directly to patients). Your organization must ensure proper classification of costs and relationships. For subrecipient relationships, your organization must ensure written subaward/subcontract agreements are in place. These written agreements must require that subrecipients comply with the same terms and conditions as the prime recipient, as applicable (e.g., financial management requirements, audit requirements). In other words, the requirements imposed on the prime recipient must "flow down" to subrecipients. Written agreements should also describe the scope of work, deliverables, etc.

Other: Include all costs that do not fit into any other category and provide a justification and narrative description of each cost in this category (e.g., provider licenses, dedicated space rental).

Indirect Costs: Indirect costs are costs incurred for common or joint objectives that you cannot readily or specifically associate with a particular program but are necessary to the operations of your organization. This could include the cost of operating and maintaining facilities, depreciation, and administrative salaries. For some institutions, the term "facilities and administration" (F&A) is used to describe indirect costs.

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You may request full indirect costs, subject to statutory and regulatory limitations and submission of an approved Negotiated Indirect Cost Rate Agreement (NICRA) established by the cognizant federal agency (typically the agency that provides the majority of the funds). If you claim indirect costs, you must submit a copy of the NICRA in **Attachment 9** of your application. If you are unable to obtain a NICRA from the cognizant agency at the time of application, you may choose to recover indirect costs using a de minimis rate. Otherwise, you may only be reimbursed for allowable direct costs.

If you cannot obtain a NICRA at the time of application, you may choose a 15 percent de minimis rate, subject to statutory and regulatory limitations.

You may use the 15 percent de minimis rate indefinitely and apply it to the Modified Total Direct Costs (MTDC). MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first $50,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs, and the portion of each subaward in excess of $50,000.

Violation of cost accounting principles is not permitted when re-budgeting or charging costs to awards. Rather, you must consistently charge costs as either direct or indirect costs. Additionally, once elected, you must apply the 15 percent de minimis rate to all existing awards. If the cognizant agency issues a NICRA after the award, the negotiated rate may not be retroactively applied.

Waived Indirect Costs: You may also choose to waive recovery of indirect costs on any award. If so, write "None Requested" in Item J of the budget.

Section F: Standards for Financial Management and Standard Funding Restrictions

If SAMHSA funds your project, your organization must follow the financial management requirements and cost principles in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards 2 CFR 200 (Subparts D and E), unless superseded by a program statute.

- Subpart D has federal financial management requirements for grant recipients.

- Subpart E has the applicable cost principles that specify allowable and unallowable expenditures.

Standards for Financial Management

Your financial management systems must meet the standards in 2 CFR 200 Subpart D. These standards require your financial management systems to retain a grant award's distinct identity to (a) permit the accurate reporting of financial results for each federal award, and (b) track expenditures to establish that funds have been used by your organization for their intended purposes, in accordance with federal statutes, regulations, and the terms and conditions of your federal award.

As a result, **you may not comingle individual federal awards with other federal and non-federal awards and expenditures**. Commingling typically occurs when an organization combines funds and expenditures from multiple grant awards into a single account.

Common Commingling Mistakes

- **Commingling Cost Centers.** Every business activity constitutes a cost center. Examples of cost centers include: a federal award, a state award, a private award, matching costs for a specific award, a self-funded project, fundraising activities, membership activities, lines of business, unallowable costs, and indirect costs. You must set up a unique account in your accounting system to capture and accumulate expenditures for each cost center, apart from other cost centers.

- **Commingling Cost Categories.** You must avoid budget fluctuations that violate programmatic restrictions. You must also avoid applying indirect cost rates to prohibited cost categories, such as equipment, participant support costs, and the portion of each subaward in excess of $50,000. As a result, you must establish unique object codes in the accounting system to capture and accumulate costs by budget category, such as salaries, fringe benefits, consultants, travel, participant support costs, and subcontracts.

- **Commingling Time Worked and Not Worked.** You cannot directly charge an award for employees' time not spent working on the award. Therefore, you may not recover paid time off (PTO), such as vacation, holiday, sick, and other paid leave, directly from awards. You must instead allocate PTO to all your awards, projects, and cost centers over an entire cost accounting period through either an indirect cost or fringe benefit rate.

- **Commingling Labor Costs - Unsupported Labor Costs**. Time and attendance sheets alone, showing an employee worked a certain number of hours during a given day or time period, are inadequate to support salaries and wages. Rather, you must support charges for direct and indirect salaries and wages by using timekeeping documentation that identifies the work performed. For example, you may use hourly timesheets that encompass all hours worked and not worked each day. The timesheet should identify the: (a) grant award, project, or cost center worked on; (b) number of hours worked on each; (c) description of work performed; and (d) PTO hours. The total hours recorded each day should align with a person's employment status in accordance with established policy (i.e., full-time employees work 8 hours each day).

- **Commingling Direct and Indirect Costs - Inconsistent Treatment of Costs.** You must treat costs consistently across all federal and non-federal awards, projects, and cost centers. For example, you may not direct-charge federal awards for costs typically considered indirect in nature, unless you do so consistently. Examples of indirect costs include administrative salaries, rent, accounting fees, and utilities. Additionally, in most cases, the cost to develop an accounting system adequate to justify direct charging of the aforementioned items outweighs the benefits. As a result, use of an indirect cost rate is the most effective mechanism to recover these costs and not violate federal financial requirements of consistency, allocability, and allowability.

Standard Funding Restrictions

In addition to 2 CFR 200, Subpart E's guidance regarding allowable/unallowable expenditures, you may not use SAMHSA funds to:

- All activities proposed in your application and budget narrative must be in alignment with the current Executive Orders (EO). For the latest guidance, please visit Presidential Actions – The White House. If an application does not align with EOs, the application will not receive funding.

- Funds cannot be used to support or provide services, either directly or indirectly, to removable or illegal aliens.

- Purchase, prescribe, or provide marijuana or treatment using marijuana. (See, 2 CFR 200.300(a) and 21 U.S.C. 812(c) and 841 for detailed information.)

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- Purchase, obtain, or distribute pipes or cylindrical objects intended to be used to smoke or inhale illegal scheduled substances.

- Pay for promotional items including, but not limited to, clothing and commemorative items, such as pens, mugs/cups, folders/folios, lanyards, and conference bags. (See 2 CFR 200.421(e)(3)).

- Pay for the purchase or construction of any building or structure to house any part of the program. Minor alterations and renovations (A&R) may be authorized for up to 25 percent of a given budget period or $150,000 (whichever is less) for existing facilities, if necessary and appropriate to the program. Minor A&R may not include any structural change, such as to the foundation, roof, floor, or exterior or loadbearing walls of a facility, or extension of an existing facility, to increase the floor area or change the facility's function and purpose. **SAMHSA must approve all minor A&R.**

- Provide inpatient treatment or hospital-based detoxification services. SAMHSA does not consider residential services as inpatient or hospital-based services.

- Pay for housing other than recovery housing, which includes application fees and security deposits.

- Make direct payments to individuals to enter treatment or continue to participate in prevention or treatment services. (See 42 U.S.C. § 1320a-7b).

  NOTE: You can provide up to $30 non-cash incentives, such as gift cards, bus passes, or gifts, to individuals to participate in required data collection follow-up. You may use incentives of this amount for participation in each required data collection follow-up interview. You cannot provide incentives for completing an intake or exit interview. For programs using contingency management, participants may not receive contingencies totaling more than $75 per budget period.

- Purchase firearms.

- Purchase sterile needles or syringes for the hypodermic injection of any illicit drug unless your state or local health department, in consultation with the Centers for Disease Control and Prevention, determines your state or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use and your program is operating in accordance with state and local laws. (See Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act Public Law 118-473, Further Consolidated Appropriations Act, 2024, Division D, Title V, Section 526.)

- Pay a program employee's direct salary more than Executive Level II pay. The Executive Level II pay amount is a person's base salary exclusive of fringe and any income that an employee may earn outside of the duties to your organization. The salary limitation does not apply to consultants but does apply to subrecipients. Note that these or other salary limitations will apply in future fiscal years, as required by law. The current salary limitation can be found in the most recent SAMHSA Standard Terms and Conditions.

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Section G: Administrative and National Policy Requirements

If SAMHSA funds your project, you must follow all terms and conditions of the Notice of Award (NoA). SAMHSA's standard terms and conditions are available on the SAMHSA website.

HHS Grants Policy Statement (GPS)

You must comply with the requirements in Parts I and II of the HHS Grants Policy Statement (GPS) unless the NoA includes statutory, regulatory, or award-specific requirements to the contrary.

HHS Award Regulations

Your program and any related activities are subject to all provisions in 2 CFR 200, other Department regulations and policies, and applicable statutory provisions in effect or implemented during the period of the award. See SAMHSA's website for more information.

Additional Terms and Conditions

Depending on your funding opportunity and proposed program, your NoA may include additional terms and conditions. These may include:

- Concerns related to confidentiality and participant protection requirements.

- Data collection and reporting requirements.

- Participation in a cross-site evaluation.

- Problems identified in the review of the application or the budget and narrative justification.

Performance Goals and Objectives

SAMHSA will hold your organization accountable for the performance targets you provide in your application. When making an annual recommendation to continue the award and the funding amount, SAMHSA program officials will consider your progress implementing the required activities and meeting your goals and objectives. In your progress report, you will also be expected to describe barriers or challenges you encountered and strategies you put in place to overcome them.

Failure to meet your stated goals and objectives may result in suspension or termination of your award or in reduction or withholding of continuation awards (see 2 CFR 200.202, 2 CFR 200.301, and 2 CFR 200.329).

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Termination of Federal Award

The Office of Management and Budget revisions to termination provisions apply to all federal awards after August 13, 2020 (see 2 CFR 200.340).

Accessibility Provisions for All Award Application Packages and Funding Opportunity Announcements

You must take reasonable steps to provide meaningful access to people with limited English proficiency and make sure your programs are accessible to and usable by persons with disabilities.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by people with limited English-language proficiency, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on your specific legal obligations for serving qualified people with disabilities, including providing program access, reasonable modifications, and effective communication (see www.hhs.gov/civil-rights/for-individuals/disability/index.html). In addition, see information below on products developed with award funds.

In addition,

- HHS-funded health and education programs must be administered in an environment free of sexual harassment.

- You must administer your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated antidiscrimination laws, see www.hhs.gov/conscience/religious-freedom/index.html.

Acknowledgment of Federal Funding

As required by HHS appropriations acts, all HHS recipients must acknowledge federal funding when issuing statements, press releases, publications, requests for proposal, bid solicitations, and other documents, such as tool kits, resource guides, websites, and presentations, describing the projects or programs funded in whole or in part with HHS federal funds.

You must clearly state: (1) the percentage and dollar amount of the total costs of the program or project funded with federal money; and (2) the percentage and dollar

amount of the total costs of the project or program funded by non-governmental sources.

Supplement, Not Supplant

You may use funds to supplement existing activities. However, you cannot use award funds to supplant current funding of existing activities. "Supplant" is defined as replacing funding of a recipient's existing program with funds from a federal award.

Mandatory Disclosures

A term may be added to the NoA that states: "Consistent with 2 CFR 200.113, an applicant, recipient, or subrecipient of a Federal award must promptly disclose whenever, in connection with the Federal award (including any activities or subawards thereunder), it has credible evidence of the commission of a violation of Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code or a violation of the civil False Claims Act (31 U.S.C. 3729-3733). The disclosure must be made in writing to the Federal agency, the agency's Office of Inspector General, and pass-through entity (if applicable). Recipients and subrecipients are also required to report matters related to recipient integrity and performance in accordance with 2 CFR 200 Appendix XII."

You must send disclosures in writing to the HHS Office of the Inspector General (OIG) at:

Office of Counsel to the Inspector General

Office of Inspector General

U.S. Department of Health and Human Services

Grant Self-Disclosures

330 Independence Avenue SW

Cohen Building, Room 5527

Washington, DC 20201

OR via email to grantdisclosures@oig.hhs.gov

Failure to make required disclosures can result in any of the remedies described in 2 CFR 200.339 (Remedies for noncompliance), including suspension or debarment (see 2 CFR part 180, 31 U.S.C. 3321, and 41 U.S.C. 2313).

System for Award Management (SAM) Reporting

A term may be added to the NoA that states: "In accordance with the regulatory requirements provided at 2 CFR 200.113, 2 CFR 25, and Appendix XII to 2 CFR 200, recipients that have currently active federal awards and procurement contracts with

cumulative total value greater than $10,000,000, must report and maintain information in SAM about civil, criminal, and administrative proceedings in connection with the award or performance of a federal award that reached final disposition within the most recent five-year period. The recipient also must make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently Responsibility/Qualification in SAM.gov [R/Q]). Full reporting requirements and procedures are found in Appendix XII to 2 CFR 200."

Drug-Free Workplace

A term may be added to the NoA that states: "You as the recipient must comply with drug-free workplace requirements in Subpart B of part 382, which adopts the Government-wide implementation (2 CFR part 182) of section 5152-5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701-707)."

Smoke-Free Workplace

The U.S. Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, certain facilities (or in some cases, any portion of a facility) prohibit smoking where regular or routine education, library, day care, health care, or early childhood development services are provided to children. See 20 USC 6081 et seq., the Pro-Children Act of 1994.

Trafficking in Persons

Awards issued by SAMHSA are subject to the requirements of 2 CFR Part 175 and 22 U.S.C. 7104(g). For the full text of the award term, go to www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-conditions.

Products Developed with Award Funds

All Information and Communications Technology (ICT) developed, funded, maintained, and used by HHS must be accessible to individuals with disabilities in accordance with Section 504 and Section 508 of the Rehabilitation Act of 1973. Content and system owners and authors are accountable and responsible for ensuring that their system(s), product(s), and/or service(s) are accessible to HHS personnel and members of the public. In particular, written materials must be 508 compliant. See https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-policy-section-508-compliance-accessibility-information-communications-technology.html.

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Publications

You must notify your Government Project Officer (GPO) of any materials based on the SAMHSA-funded project that are accepted for publication. In addition, SAMHSA requests that you:

- Provide the GPO with advance copies of publications.

- Include acknowledgment of SAMHSA as the source of funding for the program.

- Include a disclaimer that says that the views and opinions contained in the publication do not necessarily reflect those of SAMHSA or the U.S. Department of Health and Human Services and should not be construed as such.

SAMHSA reserves the right to issue a press release about any publication it deems to contain information of program or policy significance to the substance misuse treatment, substance misuse prevention, or mental health services communities.

Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment

As described in 2 CFR 200.216, you and your subrecipients are prohibited from obligating or spending award funds (to include direct and indirect expenditures, as well as cost share and program funds) to:

1. *Procure or obtain*

2. *Extend or renew a contract to procure or obtain*

3. *Enter into contract (or extend or renew contract) to procure or obtain any equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system or as critical technology as part of any system.*

As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

- For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

- Telecommunications or video surveillance services provided by such entities or using such equipment.

- Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

NOTE: The signature of the Authorized Organization Representative (AOR) on the application serves as the required certification of compliance for your organization regarding the administrative and national policy requirements.

Section H: SAMHSA Expectations

SAMHSA expects recipients to use funds to implement high-quality programs, practices, and policies that are recovery-oriented, trauma-informed, and accessible to all populations to improve behavioral health.[2] These are part of SAMHSA's core principles, as documented in our strategic plan. In addition, there are other expectations applicants must consider as they design their projects.

Recovery is a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential. Recipients promote partnerships with people in recovery from mental and substance use disorders and their family members to guide the behavioral health system and promote individual, program, and system-level approaches that foster:

- *Health*—managing one's illnesses or symptoms and making informed, healthy choices that support physical and emotional well-being;

- *Home*—having a stable and safe place to live;

- *Purpose*—conducting meaningful daily activities, such as a job or school; and

- *Community*—having supportive relationships with families, friends, and peers.

Recovery-oriented systems of care embrace recovery as:

- emerging from hope;

- person-driven, occurring via many pathways;

- holistic, supported by peers and allies;

- supported through relationship and social networks;

- involving individual, family, and community strengths and responsibility;

- supported by addressing trauma; and based on respect.

Trauma-informed approaches recognize and intentionally respond to the lasting adverse effects of experiencing traumatic events. SAMHSA defines a trauma-informed approach through:

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[2] "Behavioral health" means the promotion of mental health, resilience and wellbeing; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities.

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- *Safety*: participants and staff feel physically and psychologically safe;

- *Peer Support:* peer support and mutual self-help are vehicles for establishing safety and hope, building trust, enhancing collaboration, and using lived experience to promote recovery and healing;

- *Trustworthiness and Transparency*: organizational decisions are conducted to build and maintain trust with participants and staff;

- C*ollaboration and Mutuality:* importance is placed on partnering and leveling power differences between staff and service participants;

- *Empowerment, Voice, and Choice*: organizations foster a belief in the primacy of the people who are served to heal and promote recovery from trauma.[3]

It is critical for recipients to promote the linkage to recovery and resilience for individuals and families affected by trauma.

Tobacco and Nicotine-free Policy

You are encouraged to adopt a tobacco/nicotine inhalation (vaping) product-free facility/grounds policy and to promote abstinence from all tobacco products (except accepted tribal traditions and practices).

Reimbursements for the Provision of Services

Recipients must first use revenue from third-party payments (such as Medicare or Medicaid) from providing services to pay for uninsured or underinsured individuals. Recipients must implement policies and procedures that ensure other sources of funding (such as Medicare, Medicaid, private insurance, etc.) are used first when available for that individual. Grant award funds for payment of services may be used for individuals who are not covered by public or other health insurance programs. Each recipient must have policies and procedures in place to determine affordability and insurance coverage for individuals seeking services. Program income revenue generated from providing services must first be used to pay for programmatic expenses related to the proposed grant activities.

Recipients must also assist eligible uninsured clients with applying for health insurance. If appropriate, consider other systems from which a potential service recipient may be eligible for services (for example, the Veterans Health Administration or senior services).

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[3] https://www.samhsa.gov/find-help/trauma

Inclusion of People with Lived Experience Policy

SAMHSA recognizes that people with lived experience are fundamental to improving mental health and substance misuse services and should be meaningfully involved in the planning, delivery, administration, evaluation, and policy development of services and supports to improve processes and outcomes.

Behavioral Health for Military Service Members and Veterans

Recipients are encouraged to address the behavioral health needs of active-duty military service members, national guard, and reserve service members, returning veterans, and military families in designing and implementing their programs. Where appropriate, consider prioritizing this population for services.

Behavioral Health for Lesbian, Gay, and Bisexual (LGB) Individuals

Recipients are encouraged to address the behavioral health needs of this population in designing and implementing their programs.

Behavioral Health Crisis and Suicide Prevention

Recipients are encouraged to develop policies and procedures that identify individuals at risk of suicide/crisis, and utilize or promote SAMHSA national resources, such as the 988 Suicide & Crisis Lifeline, SAMHSA Helpline/Treatment Locator, and FindSupport.gov.

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Section I: Intergovernmental Review Requirements

This section addresses steps applicants need to take to comply with state review and comment rules, where applicable.

State Points of Contact

All SAMHSA programs are covered under Executive Order (EO) 12372. Under this EO, states may design their own processes for reviewing and commenting on proposed federal assistance. Certain jurisdictions participate in the EO process and have established a State Point of Contact (SPOC).

This requirement does not apply to American Indian or Alaska Native tribes or tribal organizations.

If your state has a SPOC:

Contact your SPOC as early as possible to let them know about your application and ask for any instructions regarding the state's review process. If your program serves more than one state, contact each state's SPOC.

The SPOC should send any state recommendations to the following address **within 60 days of the application deadline:**

Director, Division of Grants Management
Office of Financial Resources
ATTN: SPOC – *[Include the Funding Announcement Number]*
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Room 17E20
Rockville, MD 20857

If your state does not have a SPOC and you are a community-based, non-governmental service provider:

You must submit a Public Health System Impact Statement (PHSIS)[4] to the appropriate state and local health agencies in your service area **by the application deadline**. The

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[4] Approved by the Office of Management and Budget (OMB) under control no. 0920-0428; Public Reporting Burden for the Public Health System Reporting Requirement is estimated to average 10 minutes per response, including the time for copying the first page of SF-424 and the abstract and preparing the letter for mailing. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0920-0428. Send comments regarding this burden to CDC Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0428).

PHSIS informs state and local health officials of proposed health services applications submitted within their jurisdictions.

This requirement does not apply to state or local governments or American Indian/Alaska Native tribes or tribal organizations.

You must include the following in your PHSIS:

1. A copy of the first page of your application (SF-424).

2. A one-page project summary of your service population, the services you will provide, and your plans for coordination with state or local health agencies.

The appropriate state agency for you to contact is your Single State Agency (SSA) for substance abuse and mental health. If your project falls within the jurisdiction of more than one state, you should notify all appropriate SSAs. See a listing of the SSAs for substance abuse and the SSAs for mental health at www.samhsa.gov/grants/applying/forms-resources under "Additional Resources."

Review Step 3 of the NOFO carefully to determine if you must include an attachment with a copy of a letter transmitting the PHSIS to the SSA. The letter must notify the state that, if it wishes to comment on the proposal, it should send comments **withing 60 days of the application deadline** to:

Director of Grants Management
Office of Financial Resources
ATTN: SSA – (Include the Funding Announcement Number)
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Room 17E20
Rockville, MD 20857

In addition, you may ask the SSA to send you a copy of any state comments.

If you receive an award from SAMHSA, you must notify the SSA within 30 days of receipt.

CERTIFICATE OF SERVICE

I hereby certify that on July 14, 2025, I served a true and correct copy of the foregoing document on the following parties by the method(s) indicated below:

Brian C. Kipnis Annalisa L. Cravens Sarah L. Bishop Rebecca S. Cohen *Assistant United States Attorneys* Office of the United States Attorney 700 Stewart Street, Suite 5220 Seattle, WA 98101-1271 brian.kipnis@usdoj.gov annalisa.cravens@usdoj.gov sarah.bishop@usdoj.gov rebecca.cohen@usdoj.gov *Attorneys for Defendants*	☒ CM/ECF E-service ☐ Email ☐ U.S. Mail ☐ Certified Mail / Return Receipt Requested ☐ Hand delivery / Personal service

I declare under penalty of perjury under the laws of the United States and the State of Washington that the foregoing is true and correct.

DATED this 14th day of July, 2025.

/s/ Gabriela DeGregorio
Gabriela DeGregorio
Litigation Assistant
Pacifica Law Group LLP

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